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DATE

SUBJECT

EPA Registration Number 239-2458 Orthocide Vitavax 20-20 Seed Protectant

FROM

Deloris F. Graham NAL 3/ 1 12 FH9/TSS マ シバケン

004666

Henry Jacoby TO

Product Manager (21)

Applicant: Chevron Chemical Company

Ortho Agricultural Chemicals Division

940 Hensley Street

Richmond, California #4804

Active Ingredients 159 - Captan).... 199 14 Related Derivatives 16-14 - Carbofxini 20% 601 Inert Ingradients.....

Background: Submitted Acute Oral, Eye Irritation and Primary Dermal Irritation Studies in response to the Carborkin Registration Standard. Studies conducted by Chevron. Data under accession number 246774. Method of support not indicated.

Recommendation

- (1) FHB/TSS finds the data acceptable to support the conditional registration of this product in compliance with the carboxin registration standard. However, for future submissions please note:
 - (a) In the Eye Irritation study, nine rabbits (six with treated unwashe: eyes and three with treated washed eyes) must be used.
 - (b) In the Primary Dermal Study, four test sites (2 abraded and 2 intact) per animal must be used.
- (2) Based on the Eye Irritation study the appropriate signal used is WARNING.

Label:

(1) Proposed labeling is acceptable.

Review:

(1) Acute Oral Toxicity Study: Chevron: Socal 1074/31:56; December 1, 1977.

Procedure: Five groups. Three of the groups consisted of 5M and 5F Sprague-Dawley rats, one consisted of 10M and 5F and one consisted of 10M and 10F. Each received one of the following doses: 3.3, 5.0, 7.5, 10, 15 g/kg. The rats weighed between 200-277 g. Observations were made daily for 14 days. Necropsy performed or all animals.

EPA FORM :320-6 (REV 3-76)

Results: At 5 g/kg, 1/10 M died; at 7.5 2/5 F died; at 10 g/kg, 7/10 M and 9/10 F died; at 15 g/kg, 5/5 M and 5/5 F died.

Toxic signs observed included diarrhea, depression, weakness, convulsions, chewing of extremities, reduce food consumption, and weight loss.

Necropsy revealed enlarged liver and spleen; reduced body fat; kidneys which appeared necrotic had small masses attached to them.

LD50 for males was 8.4 g/kg with confidence limits between 5.8 and 12 g/kg. LD50 for females was 7.3 g/kg with confidence limits between 5.0 and 11 g/kg.

Study Classification: Core Guideline Data

Toxicity Category: IV - CAUTICM

(2) Eye Irritation Study: Chevron; Socal 1072/30:74; October 10, 1977.

Precedure: A 0.1 ml of the test material was applied to one eye each of 6 rabbing. Observations were made at 1, 24, 48, 72 hours and 7, 10 and 14 days.

Results: At day 1, 2/6 animals had corneal opacity $(1/6 + 5 \cdot 1/6 = 10)$; 6/6 iris irritation (6/6 = 5), redness (1/6 = 2, 5/6 = 3), chemosis (1/6 = 1, 2/6 = 2, 3/6 = 3), discharge (2/6 = 2, 4/6 = 3). Roughened cornea also observed.

At day 3, 4/6 had corneal opacity (3/6 = 5, 1/6 = 10), iris irritation (4/6 = 5); 6/6 redness (2/6 = 2, 4/6 = 3); 5/6 chemosis (2/6 = 1, 3/6 = 2), discharge (1/6 = 1, 4/6 = 2).

At day 7, 2/6 corneal opacity (1/6=5, 1/6=13); 5/6 redness (1/6=1, 4/6=2); 4/6 discharge (3/6=1, 1/6=2). Roughened cornea and pannus also observed.

At day 14, pannus present and roughened cornea; 1/6 redness (1/6 = 1).

Study Classification: Core Minimum Data. Nine rabbits (6 with treated unwashed eyes and 3 with treated washed eyes) must be used.

Toxicity Category: II - WARNING

(3) Primary Dermal Irritation Study: Chevron; Socal 1073/30:75; October 13, 1977.

Procedure: Each of six rabbits received 0.5 g of the test material at one intact and one abraded skin site under occlusive wrap for 24-hour exposure under occlusive wrap. Observations made at 24, 48, 72 hours and at 7 days.

Results: At 24 hours, slight to moderate erythema (scores 1 to 3) and slight to well defined erythema (scores 1 to 2) in all six rabbits. At 72 hours, 2/6 slight erythema (score of 1). At day 7, no irritation present. Primary irritation score was 1.8.

Study Classification: Core minimum data. Four test sites (2 abraded and 2 intact) per animal must be used.

Toxicity Category: IV - CAUTION

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